

1 "HEAT TRANSFER DEVICES"

2

3 The present invention relates to improvements for
4 catheters having a heat transfer device at or near
5 their distal end.

6

7 One of the present constraints concerning manufacture
8 of catheters designed to monitor various cardiac
9 output data is the manner and form of the required
10 heat transfer device system. One present form of
11 heat transfer device involves a thermal coil radially
12 disposed about the catheter body to form a generally
13 tubular coil which extends along the outside wall of
14 the catheter. Such a heat transfer device is shown
15 in US 5509424. However, such heat transfer coils
16 require time and effort to wind and form and also
17 restrict the possible miniaturisation of such
18 catheters for use in paediatrics.

19

1 It is an object of the present invention to provide
2 improvements to the manner and nature of heat
3 transfer devices for use with catheters.
4

5 Thus, according to one aspect of the present
6 invention, there is provided a catheter having a heat
7 transfer device at or near its distal end, wherein
8 the heat transfer device is layered or coated onto or
9 into the catheter wall.
10

11 In one embodiment, the heat transfer device is a
12 flexible film having one or more electrical resistor
13 flow paths thereon or therethrough, which film is
14 locatable around the catheter wall.
15

16 Such films can include flexible metal films on which
17 one or more electrical paths have been etched or
18 otherwise created. Alternatively, one or more
19 electrical paths could be added onto a plastic film
20 backing. The form of addition includes any type of
21 deposition or coating, and the one or more electrical
22 paths could be formed by etching, etc to form the
23 resistor structure.
24

25 One or more temperature sensors or sensor leads could
26 be included on or within the heat transfer device
27 film to monitor the temperature of the electrical
28 path(s), and thus the temperature of the overall heat
29 transfer device.
30

1 Suitable backing materials include PVC, polyurethane,
2 silk, synthetic silk, silicon rubber, ElastonTM etc,
3 possibly about 20-80 microns thick, and suitable thin
4 high resistant metal films include nickel, chromium
5 or nickel-chromium. These can be deposited on the
6 plastic backing material, and patterned using a
7 photolithography mask to form the resistor structure.

8
9 On top of the resistor structure could be located a
10 suitable insulator like parylene C, followed by
11 deposition of a suitable temperature sensing means
12 e.g. thermistors or platinum. Finally the outer
13 surface may be coated with a silver or gold layer,
14 possibly 5-10 microns thick. This layer assists in
15 averaging heat distribution. Gold and/or silver are
16 suitable as they are conductive and biocompatible.
17 Optionally a further layer of parlyene C or other
18 insulation is added as the outer layer.

19
20 Possible arrangements for the electrical paths and
21 temperature sensing means across the backing material
22 are shown in Figures 3 and 4 of the accompanying
23 drawings.

24
25 This form of heat transfer device can be fixed around
26 a catheter at or near its distal end. Preferably the
27 film is about 0.5-2.0 cm long, in order for it to
28 remain within the main pulmonary artery trunk. The
29 film could be fixed around the catheter starting at
30 about 4-5 cm from the tip, and in the case of a PVC

1 catheter body, the PVC film heat transfer device
2 could be bonded by solvent.

3
4 Such a heat transfer device could be adapted to fit a
5 catheter less than 7F diameter (2.3mm). More
6 preferably the heat transfer device can be
7 incorporated in a catheter of 3-5F (1-1.67mm)
8 diameter. The heat transfer device should not
9 increase the outer diameter of the catheter more than
10 about 0.3F (0.1mm).

11
12 Using the same technique, a similar film could be
13 formed purely for temperature sensing. The
14 temperature sensing material could be deposited on a
15 backing film, followed by parylene (and gold)
16 coatings. Such a temperature sensor could be
17 positioned to 2-4 cm proximal to the heat transfer
18 device. Optionally a further layer of parylene C or
19 other insulation is added as the outer layer.

20
21 According to another embodiment of the present
22 invention, the heat transfer device is disposed onto
23 the catheter wall by any known method of deposition,
24 eg plasma deposition, printing, electroplating onto
25 plastic, photo lithography etc. Application by
26 printing uses eg conductive ink, or a conductive
27 layer, with subsequently etching. This method of
28 deposition can use any suitable resistive material.
29 In addition, the temperature sensor material could be
30 similarly applied.

31

1 According to a second aspect of the present
2 invention, there is provided a catheter having a
3 length of its outer wall formed wholly, substantially
4 or partly from doped material able to act as a heat
5 transfer device upon application of power
6 therethrough.

7
8 This form of heat transfer device could be formed as
9 an inherent part of the catheter wall, rather than as
10 a separate addition of a heat transfer device to the
11 catheter. The catheter wall is sufficiently doped
12 with a resistive material or ingredient able to pass
13 electrical current therethrough, without affecting
14 its other properties. Any conductive material could
15 be suitable, eg silver, gold.

16
17 According to a third aspect of the present invention,
18 there is provided a catheter wall having one or more
19 metal wires therethrough.

20
21 By locating the electrical connections within the
22 catheter body wall, separate lumens for electrical
23 connections to its distal end within the catheter
24 interior are no longer required. These wires can
25 also provide the catheter with the desired or
26 required stiffness.

27
28 The wire(s) can be formed from any suitable metal, eg
29 copper. Preferably, each wire is co-extruded within
30 the catheter body.

31

1 More preferably, there are one or more sets of
2 electrical wires in the catheter wall, each set
3 having the required number of wires for the desired
4 operations.

5
6 In one embodiment of the present invention, the
7 catheter body has three sets of wires, each set
8 comprising two wires. One set of wires is for a
9 heating element, and the other two sets are for each
10 of two temperature sensing elements located on or
11 along the catheter wall, or one set for measuring
12 ambient blood temperature, and the other set for
13 measuring the temperature of the heat transfer
14 device, or any other suitable combination of
15 measurements.

16
17 The wire or wires inside the catheter wall should be
18 easily exposable and thus connectable to the required
19 electrical units to which they correspond. Any
20 exposed wire could be covered by a suitable insulator
21 such as vinyl adhesive, or urethane potting compound.

22
23 An example of this aspect of the present invention is
24 shown in Figure 2 of the accompanying drawings.

25
26 According to a preferred embodiment of the present
27 invention, there is provided a catheter combining the
28 first and third aspects described above.

29
30 One advantage of the use of one or more aspects of
31 the present invention as described above is the

1 ability to reduce the size of the catheter, more
2 particularly for paediatric use. A catheter wherein
3 the electrical wires required for the heat transfer
4 device, etc are co-extruded within the catheter body,
5 means that the catheter may only need a single distal
6 lumen, (possibly 0.5-0.7 mm diameter) for solution
7 infusion and pressure monitoring.

8
9 The novel apparatus and methods of the present
10 invention could also be used in non-medical fields
11 using heat transfer devices at or near the distal
12 ends of elongate tubing to be located in remote
13 locations. Such fields include aeronautics, any
14 fluid flow analysis, food and drink processing and
15 monitoring, water and sewerage management, chemical
16 engineering, fuel supply to engines, etc.

17
18 The present invention is also particularly applicable
19 to the paediatric catheter field.

20
21 Embodiments of the present invention are shown by way
22 of example only in the accompanying diagrammatic
23 drawings in which:

24
25 Figure 1 is side view of a paediatric catheter;

26
27 Figure 2 is a radial cross-sectional view of a
28 catheter wall having electrical wires located
29 therein;

30

1 Figure 3 is an example of a heat transfer device film
2 for application around a catheter body;

3

4 Figure 4 is an example of a temperature sensor for
5 application around a catheter body.

6

7 Figure 5 is a longitudinal cross-sectional view of a
8 catheter body having a heat transfer device
9 therearound.

10

11 Figures 6a, b and c show a method of preparing a
12 catheter having a heat transfer device.

13

14 The dimensions referred to in relation to
15 accompanying diagrammatic drawings are illustrative
16 only, and in no way limiting or essential.

17

18 Referring to the drawings, Figure 1 shows the general
19 form of a paediatric pulmonary artery catheter, which
20 may be 70-100 cm long. At one end, such catheters
21 generally have a connection 2, for example, to a
22 TRUCCOM™, and a distal lumen 4. Such catheters are
23 generally 3-5F size, i.e. approximately 1-1.67mm
24 diameter.

25

26 For all such catheters, the heat transfer device
27 should preferably be in the range 0.5-2.0 cm long in
28 order to remain within the main pulmonary artery
29 trunk. The catheter body shore hardness should be
30 about 45-55D for proper handling during insertion

1 into patients. Use of softer materials may be
2 possible, but may require the additional use of a
3 wire to stiffen the catheter body allowing
4 manoeuvrability during insertion.

5
6 In the versions of the present invention based on the
7 layering or coating of the transfer device onto or
8 into the catheter wall, the heat transfer device
9 should not increase the outer diameter of the
10 catheter more than 0.3F (0.1mm).

11
12 Figure 1 shows a schematic representation of a heat
13 transfer device 6 according to the present invention
14 2cm long, and located 4cm from the end of the
15 catheter. Thereafter is located a temperature sensor
16 8, approximately 0.3cm long.

17
18 Figure 2 is a cross-section of a catheter wall 10
19 wherein six copper wires 12 are co-extruded with the
20 catheter body so as to be located in the catheter
21 wall 10. Of the six wires, two are located for the
22 heating element, and two for each of two temperature
23 sensing elements (not shown). Thus, the catheter
24 only has a single distal lumen 14, 0.5mm diameter for
25 solution infusion and pressure monitoring.

26
27 Figure 3 is an example of a flexible metal film heat
28 transfer device 20 according to the present
29 invention. The film consists of a thin high
30 resistance metal film, e.g. of nickel, chromium or
31 nickel-chromium, deposited on a PVC film 22, e.g. of

1 25-50 microns thick. The resistor wire 24 in Figure
2 3 can be patterned using a photolithography mask.
3 The device 20 includes temperature sensor leads 26.
4

5 Figure 4 shows a possible pattern for temperature
6 sensor leads 30 on a similar PVC film 32 to act as a
7 temperature sensor as shown in Figure 1. It is
8 similarly made to the device in Figure 3, but only
9 the temperature sensing material is deposited
10 followed by Paralyene C and gold coatings.
11

12 Figure 5 shows a longitudinal cross-section of a
13 catheter having a heat transfer device 34 based on
14 that shown in Figure 3. Around the catheter body 36
15 is a PVC film 0.05mm thick. The resistor and
16 temperature sensor leads are on the PVC film, which
17 is then coated with a suitable insulator such as
18 Parylene C, possibly of 0.005mm thickness. The outer
19 surface is coated with a silver or gold layer
20 (suitably 5-10 microns thick).
21

22 As shown in Figures 6a-6c the overall heat transfer
23 device 34 can be conjoined with the catheter body 36
24 using any suitable means such as a solvent. A
25 temperature sensor 40 such as that shown in Figure 4
26 is also conjoined with the catheter body 36, e.g. 2-4
27 cm proximal to the device 34. Thereafter, and as
28 shown in Figures 6a-c, the wires 38 inside the
29 catheter wall 36 are then exposed and the heat and
30 temperature sensing wires are then connected and

- 1 covered by a vinyl adhesive or another suitable
- 2 insulator.
- 3
- 4